UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 28, 2000

MEMORANDUM

SUBJECT: **MALATHION Phase 2 Response.** HED's Comments on Cheminova's 30-day (error only) Response to the HED Preliminary Risk Assessment dated February 10, 2000.
Chemical No. 057701
Case No. 0248
Barcode: D265563

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This memorandum is HED's Phase 2 response to the document *Comments from Cheminova A/S on EPA's Draft Preliminary Risk Assessments for Malathion* provided by the registrant's sponsor, Jellinek, Schwartz & Connolly, Inc., dated March 29, 2000. HED's response addresses Cheminova's "error only" comments specific to HED's Science Chapters and the various Committee Memoranda supporting the Preliminary Risk Assessment for Malathion dated February 10, 2000. HED further makes note of mitigation issues which may be further considered during Phase 4. For easy reference, HED has responsed to Cheminova's concerns using outline headings directly from Cheminova's submission, noting page numbers for clarity; topics pertinent to EFED documents and those requiring

no HED response have been omitted. Cheminova's comments appear in italics and are given verbatim or paraphrased for brevity.

The following documents have been revised and provide the basis for HED's revised Risk Assessment:

Cancer Assessment Document #2: Report of the 12-April-2000 Meeting: Evaluation of the Carcinogenic Potential of Malathion. Cancer Assessment Review Committee. Copley (04/28/2000)
Malathion: Revised NOAEL for Derivation of the Chronic Reference Dose. Rowland (04/26/2000)
Revised Occupational and Residential Exposure Assessment. Jack Arthur (04/26/2000; D264848)
Revised Toxicology Chapter. Yung G. Yang (04/27/2000; D265266)
Preliminary Dietary Risk Assessment (Revised). Richard Griffin (04/27/2000; D265501)

This response memorandum was prepared with additional input from the following Malathion Team members: Brian Dementi, Ph.D., Toxicologist; Jerome Blondell, Ph.D., Health Statistician; Jack Arthur, Environmental Scientist; Nancy McCarroll, Toxicologist; and Clark Swentzel, Branch Chief.

RDI: BRSrSci:ANielsen

II. CHEMINOVA'S COMMENTS ON ERRORS	
A. ERRORS IN THE DOCUMENT ENTITLED "CANCER ASSESSMENT DOCUMENT: EVALUATION OF THE CARCINOGENIC POTENTIAL OF MALATHION" DATED FEBRUARY 2, 2000	
Cheminova's Comment	**HED's Response**
Cheminova itemized unclear and/or incorrect statements in the Executive Summary, page iv, 2nd paragraph; Executive Summary, page v, first paragraph; and on Page 29, first paragraph, last sentence.	Revision of these sections to reflect the combined summary of the 10-February-2000 report and the CARC meeting 12-April-2000 eliminates the need to address specific details of Cheminova's concerns.
Page 28, first paragraph, line 7: EPA states that "For cholinesterase inhibition, the overall NOAEL was 50 ppm and the LOAEL was 5000 ppm..." in the subchronic inhalation toxicity study in the rat. However, based on statistically significant inhibition, 5000 ppm was a clear NOAEL and 20,000 ppm was the LOAEL for brain cholinesterase inhibition in this study.	Cheminova's issues regarding non-cancer endpoints for inhalation risk assessment are addressed in Section IV.C of this response document.
B. ERRORS IN THE DOCUMENT ENTITLED "MALATHION TOXICOLOGY CHAPTER OF THE REREGISTRATION ELIGIBILITY DOCUMENT (RED)" DATED MARCH 24, 1998	
Cheminova's Comment	**HED's Response**
Cheminova requests that data requirements for subchronic and chronic dog toxicity studies and a subchronic inhalation toxicity study in the rat be clarified because Table 1 designates these requirements satisfied and the HIARC reports require additional testing.	Additional testing is required. The requirements for these study data, consistent with the HIARC Report, will be included in the revised MalathionToxicology Chapter.
On page 8, second paragraph, line 2: the malathion purity should be 96.4%, not 97.1%.	HED agrees that 96.4% was reported as a test purity; however, 97.1% represents the mean of three purity assays.
C. ERRORS IN THE DOCUMENT ENTITLED "MALATHION : REVISED NOAEL FOR DERIVATION OF THE CHRONIC REFERENCE DOSE- REPORT OF THE HAZARD IDENTIFICATION ASSESSMENT REVIEW COMMITTEE" DATED NOVEMBER 1, 1999	
Cheminova's Comments	**HED's Response**
Page 2, paragraph 2, line 2: the malathion purity should be 96.4%, not 97.1%. In addition, the mid dose level should be 6000 ppm, not 600 ppm.	HED agrees that 96.4% was reported as a test purity; however, 97.1% represents the mean of three purity assays. HED concurs that the mid dose level should be 6000 not 600 ppm..

Page 2, Paragraph 4, lines 2 and 3: the dose levels listed in parentheses should be 100 ppm for 1 to 16 weeks and 50 ppm for 18 to 102 weeks.	HED concurs that the correct dose levels are 100/50.
D. ERRORS IN THE DOCUMENT ENTITLED "MALATHION REEVALUATION: REPORT OF THE HAZARD IDENTIFICATION ASSESSMENT REVIEW COMMITTEE" DATED DECEMBER 22, 1998	
Cheminova's Comments	**HED's Response**
Cheminova itemized unclear and/or incorrect references and information on pages 4, 5, 9, 20, and 21 of the 22-December-1989 HIARC Document.	HED acknowledges Cheminova's comments on the designated pages of the 22-December 89 HIARC Document. The Document will be amended appropriately.
E. ERRORS IN THE DOCUMENT ENTITLED "MALATHION REEVALUATION: REPORT OF THE HAZARD IDENTIFICATION ASSESSMENT REVIEW COMMITTEE" DATED DECEMBER 17, 1997	
Cheminova's Comments	**HED's Response**
Cheminova itemized unclear and/or incorrect references and information of pages 51 and 52 of the 17-December-1997 HIARC Document.	HED acknowledges Cheminova's comments on the designated pages of the 17-December-1997 HIARC Document The Document will be amended appropriately.
Page 54, under Dose and Endpoint for Risk Assessment: the word "plasma" should be deleted from the first sentence because there was no statistically or biologically significant inhibition of plasma cholinesterase for males or females in the 300 ppm dose group in the 21-day rabbit dermal toxicity study.	HED acknowledges Cheminova's comment and will amend the document to state: " Dose and Endpoint for Risk Assessment: NOAEL=50 mk/kg/day based on significant inhibition of red blood cell and brain cholinesterase activity at 300 mg/kg/day (LOAEL). Plasma cholinesterase activity was also inhibited at the LOAEL, however, the decrease was not statistically significant."
F. ERRORS IN THE DOCUMENT ENTITLED "MALATHION: OCCUPATIONAL AND RESIDENTIAL EXPOSURE AND RISK ASSESSMENT FOR THE RED DOCUMENT" DATED SEPTEMBER 16, 1999	
Cheminova's Comments	**HED's Response**
In Table 6, under scenario 1c., the dermal unit exposure is listed as 0.23 mg/lb ai for the "gloves" scenario. The correct dermal unit exposure is 0.023 mg/lb ai.	HED agrees and the correct unit exposure will be used to recalculate the affected scenarios.
On page 39, the abbreviations, $LADD_{int}$ and $LADD_{abs}$ are both used to mean the same thing. Be consistent in the use of this abbreviation.	This issue is moot since HED is no longer estimating a quantitative cancer risk.

EPA is not consistent in how many significant figures it presents its exposure calculations. For example, unit exposures are specified to two significant figures, so the associated exposure estimates should not contain more than two significant figures.	Tables have been revised to be more consistent in using the appropriate number of significant figures in the data.
Inconsistent and incorrect scientific notation has been used. EPA should use the format 1E-6 or 1E-06 to represent the number 0.000001, in the text and spreadsheets, respectively.	The text and tables have been revised to consistently use the format suggested by the registrant.
III. CARCINOGENICITY CLASSIFICATION FOR MALATHION	
A. NEW PATHOLOGY WORKING GROUP REVIEW	
Cheminova's Comments	**HED's Response**
Following procedures described in PR Notice 94-5, Cheminova requested a pathology peer review of all liver slides from female F-344 rats. This review was conducted on March 14, 2000 by Dr. William Busey of Experimental Pathology Laboratories, Inc. A Pathology Working Group (PWG) was convened on March 15, 2000 at Huntingdon Life Sciences and the Report of the PWG evaluation dated March 17, 2000 was submitted to the Agency on March 20, 2000. Because the PWG determined that there were no carcinomas at any dose level, no adenomas in the 6,000 ppm dose group, and no adenomas related to treatment at the 500 ppm dose level, Cheminova believes that CARC must reconsider its classification of malathion as a "likely human carcinogen".	HED's CARC accepted the results of the Pathology Working Group reevaluation of the rat liver slides and is using the new tumor incidences in the weight of evidence. The conclusions of the PWG were considered by HED's CARC on April 12, 2000. The Committee concluded that although the incidence of liver tumors in female rats was observed only at an excessively toxic dose (12,000 ppm), it provided evidence of carcinogenicity because: 1) the incidence was statistically significant by pair-wise comparison; 2) there was a statistical trend; 3) the incidence was outside the range of both the testing facility and NTP historical control data bases. Based on this information and other weight of evidence, the CARC classified malathion as **"suggestive evidence of carcinogenicity but not sufficient to assess human carcinogenic potential"** by all routes of exposure. Refer to Cancer Assessment Document #2: Report of the 12-April-2000 Meeting: Evaluation of the Carcinogenic Potential of Malathion. Cancer Assessment Review Committee. Copley (04/28/2000)

B. CHEMINOVA'S CONCERNS ABOUT CARC'S ASSESSMENT OF MALATHION CHRONIC BIOASSAYS	
Cheminova's Comments	**HED's Response**
Page 15 Cheminova's Position – a. Rat: Liver Tumors	The CARC has already accepted the PWG report and agrees that there is an increased incidence of hepatocellular adenomas only at 12,000 ppm, a dose with excessive toxicity.
Page 16 Cheminova's Position – b. Rat: Nasal Tumors	The CARC has reevaluated these tumors and concluded that it can not be determined whether they are due to treatment of random occurrence. It should be noted that in the females, the 2 tumors occur in section 5, a section where these is little evidence of inflamation in the nasal mucosa. The CARC does not feel that a possible systemic effect can be excluded. A discussion of the historical control data is in the body of the 28-April-2000 CARC report.
Page 20 – c. Mouse Oncogenicity Study	There is no disagreement with Cheminova's statement that "…there is no evidence of carcinogenicity in the mouse at levels below those causing excessive toxicity."
Page 20 – D. Other Studies Should be Taken into Account	The CARC routinely considers all available data when evaluating the weight of the evidence. It should be noted that the CARC does not routinely "**discard or discount**" doses where there is evidence of excessive toxicity. This information is considered together with the remainder of the data base as required by the draft cancer guidelines. The weight that is placed on tumors that occur at these doses depends on the what else is observed in the data base.

C. CHEMINOVA'S CONCERNS ABOUT CARC'S GENOTOXICITY ASSESSMENT	
Cheminova's Comments	**HED's Response**
Page 22 -- b. Studies from the Open Literature Cited by CARC Need Further Evaluation. Cheminova disagreed with the Agency's use of the phrase: "overwhelming confirmation from the published literature demonstrating that malathion is genotoxic..."	The publication in question (Flessel et al., 1993) was cited in Section IV., D. (Mutagenicity, Other Information) of the CARC's assessment of the genotoxicity of malathion. This overview of the genetic toxicology of malathion, along with other available literature was used to draw the conclusion that malathion was clastogenic both *in vitro* and *in vivo* in the earlier cancer peer review of malathion (September 24 and October 8 and 15, 1997). At the time this document was prepared, information regarding the role of cytotoxicity in false positive cytogenetic assays, which was presented at the March 1999 International Workshop on Genotoxicity Test Procedures and has ben recently published (Galloway, 2000), were not available to the committee. In light of this information, the issue of the clastogenicity of malathion was revisited at the June 23, 1999 CARC meeting. To eliminate confusion, the phrase: "overwhelming confirmation from the published literature demonstrating that malathion is genotoxic..." will be replaced in the revised document with: "The overall assessment indicating positive clastogenicity should be viewed with caution."
Page 22 -- b (Cont'd). Cheminova claims that the CARC relied solely on the Flessel et al. review article and not on the primary references in reaching the conclusion about the mutagenicity/clastogenicity of malathion.	On the contrary, the conclusion that positive results were obtained at cytotoxic doses and the induction of unstable structural chromosome cast doubts on the relevance of the findings comes from a review of the individual studies.
Page 22 -- b (Cont'd). Cheminova believes that much greater weight should be given to the guideline studies.	High confidence is given to the acceptable guideline studies. However, HED considers all of the available data (submitted and published) in a weight-of-the-evidence (WOE) approach. In the interest of public health, the CARC will continue to use both the guideline studies and the data from the open literature to insure that a complete and through analysis of the test material is prepared. This approach will provide the risk assessors the opportunity to make informed decisions in the risk assessment.

Page 22 -- c. Electrophilicity Issue is Irrelevant: *Cheminova believes that the electrophilicity issue raised by the CARC for malathion is irrelevant.*	We disagree with this comment. The role of the CARC is to look at all of the available data and particularly, note areas of concerns and/or uncertainties and list reasons for this concern. The malathion issue of electrophilicity is a good example of the application of the WOE approach used by the CARC. The inclusion of Ashby and Tennant (1991), which post-dates the reference cited by the registrants's representative was intended only as additional support regarding electrophilicity. However, even if this reference is removed, we continue to have concerns. To put these concerns into a proper perspective, relative to the available mutagenicity data for malathion, the following statement will be added to the revised document. "The Committee concluded that the weight-of-the-evidence neither supports a mutagenic hazard nor a role for mutagenicity in the carcinogenicity associated with malathion."
D. EPIDEMIOLOGY	
Cheminova's Comments	**HED's Response**
Cheminova submitted the report entitled "Mortality and Incidence of Cancer Among Employees at Cheminova Agro" to EPA along with their comments.	The Danish study did not reveal any increase in mortality or cancer incidence that could be attributed to their exposures. It appears that only about half of the employees may have had significant exposure to organophosphate insecticides and no measurements were provided to assess the level of those exposures. Also, there was no measurement of the exposures to specific organophosphates (e.g., parathion, malathion). Given the limited period of follow up, the relatively small numbers employees with significant exposure, and the lack of measured exposure to malathion, this study should not be used to draw conclusions about the presence or absence of risk of cancer from exposure to malathion. HED's CARC does not feel that the information provided would alter the cancer classification of "suggestive."

E. CHEMINOVA'S CONCLUSION ON THE WEIGHT OF EVIDENCE REGARDING THE CARCINOGENICITY CLASSIFICATION OF MALATHION	
Cheminova's Comments	**HED's Response**
Cheminova believes the new Pathology Working Group findings alone require CARC to reconsider its classification of malathion as a "likely human carcinogen".	Based on the Pathology Working Group liver reevaluation and a reevaluation of the oral, nasal and mutagenicity data, the CARC has revised the weight of evidence and cancer classification from "likely" to "suggestive."
IV. TOXICOLOGY AND ENDPOINTS FOR THE RISK ASSESSMENTS	
C. TOXICITY ENDPOINTS FOR THE CHRONIC DIETARY RISK ASSESSMENT	
Cheminova's Comments	**HED's Response**
The chronic reference dose (RfD) that was calculated in the 1997 HIARC document was based on the chronic NOAEL corresponding to 4 mg/kg/day (100/50 ppm). This number has been revised to 2.4 mg/kg/day. EPA's recalculations involved assessment of mean dietary intake of malathion for the low dose group from weeks 18 through 102 (when the dose level was decreased from 100 ppm to 50 ppm because of RBC cholinesterase inhibition at the 3-month interval). Cheminova confirmed EPA's calculations. *EPA has also recalculated mean test substance intake for all other dose groups and has presented them on page 3 of the "Revised NOAEL for Chronic RfD" document. EPA's revised numbers are approximately 10% lower than those calculated by the laboratory. Cheminova was not able to reproduce EPA's calculations. Cheminova requests that EPA provide an explanation of how it has recalculated these numbers.*	The calculations of mean test substance used in the chronic toxicity/carcinogenicity study in rats (MRID 43942901) were included as attachments to Brian Dementi's October 18, 1999 memorandum to Jess Rowland, HIARC co-chairman. The Agency will provide the registrant with this memorandum. It is difficult to address this putative discrepancy, particularly since the registrant has not presented their calculations. HED believes the likely source of the difference is attributable to disproportionately greater weight having been given in the study report to mean intake values for the first 16 weeks than to those for the remaining 86 weeks of the 102 week study.

D. TOXICITY ENDPOINT FOR THE SHORT-TERM INHALATION EXPOSURE RISK ASSESSMENT	
Cheminova's Comments	**HED's Response**
Cheminova disagrees with EPA's use of a lowest-observed-adverse effect level (LOAEL) of 0.1 mg/L from the 90-day rat inhalation study for assessing short-term inhalation exposure risks for the following reasons: ** Cheminova believes that the 0.1 mg/L value from the 90-day inhalation study is a NOAEL rather than a LOAEL (see Section IV.I.2). Based on statistically significant inhibition of plasma, RBC, and brain ChE activities at doses greater than 0.1 mg/L, 0.1 mg/L is a clear NOEL in this study.* ** The results from a 90-day inhalation study are not appropriate for assessing potential risks from short-term (defined by EPA as 1 to 7 days) inhalation exposure. Cheminova believes that data from a study with exposure duration of up to 7 days would be more appropriate for this risk assessment.* *However, in light of the histopathological findings occurring in the 90-day inhalation toxicity study at and above the lowest dose level and the absence of a short-term NOEL, Cheminova is considering conducting new studies, using a tiered approach.*	The selection of a LOAEL of 0.1 mg/L from the 90-day rat inhalation study was based not only on inhibition of plasma, RBC, and brain ChE activities but on treatment-related histopathological lesions seen in the respiratory epithelium of both sexes of rats at all concentrations tested. HED's HIARC considered the 90-rat inhalation study representative of short-term exposure because nasal lesions and cholinergic signs were also observed in the two-week range finding study (MRID 43266601). HED's HIARC has noted that a 90-day inhalation toxicity study in the rat is required to fully characterize the inhalation hazard of malathion.
F. TOXICITY ENDPOINT FOR THE INTERMEDIATE-TERM INHALATION EXPOSURE RISK ASSESSMENT	
EPA is using what it considers to be the LOAEL from the 90-day inhalation toxicity study (0.1 mg/L), with a 10x-uncertainty factor, to assess potential risks for intermediate-term inhalation exposure. As mentioned before, Cheminova believes a clear NOAEL of 0.1 mg/L for plasma, RBC, and brain ChE inhibition was established in this study. However, in light of the histopathological findings occurring in this study at and above the lowest dose level, Cheminova is considering conducting new studies, using a tiered approach.	See response to "IV.D" above.

H. TOXICITY ENDPOINT FOR THE LONG-TERM INHALATION EXPOSURE RISK ASSESSMENT	
EPA is using what they consider to be the LOAEL from the 90-day inhalation toxicity study (0.1 mg/L), with a 10x-uncertainty factor, to assess potential risks for long-term inhalation exposure. As mentioned before, Cheminova believes a clear NOAEL of 0.1 mg/L for plasma, RBC, and brain ChE inhibition was established in this study. However, in light of the histopathological findings occurring in this study at and above the lowest dose level, Cheminova is considering conducting new studies, using a tiered approach.	See response to "IV.D" above.
I. TOXICOLOGY DATA REQUIREMENTS	
Cheminova's Comments	**HED's Response**
1. 90-Day Dog Toxicity Study: *EPA is requiring a 90-day feeding study in dogs because the available 1-year study is unacceptable. EPA classified the 1-year study as core-supplemental mainly because a NOEL for cholinesterase inhibition was not identified. Submitted with Cheminova's comments were data from a 28-day dog toxicity study.* *Cheminova believes that the data provided in the 1-year feeding study in dogs and the 28-day dog toxicity study should be sufficient for characterizing the toxicity of malathion in non-rodent species. Conducting an additional 90-day feeding study in dogs will provide no data that would alter the present dietary and non-dietary risk assessments.*	The December 22, 1998 HIARC report "....concluded that a 90-day study in dogs is required and recommended that the Registrant consult the Agency for study design and protocol prior to initiation of this study. In the recently submitted 28-day study of malathion in the dog (MRID 45077703; report issued April 8, 1988), malathion (a.i. 92.4%) was tested by daily capsule administration for 28-days at dosage levels of 0 (control), 125, 250 and 500 mg/kg/day. There were 3 dogs/sex/group tested. The following observations reflect a *cursory* inspection of results presented in this submission. Blood cholinesterase assays were performed at 15 days and at term. Evidently brain cholinesterase was not assayed. It was concluded based upon both plasma and erythrocyte cholinesterase inhibition that the NOAEL was less than 125 mg/kg/day, at which dose level plasma and erythrocyte cholinesterase inhibitions, both sexes combined, were 23% and 17%, respectively. A more remarkable effect for erythrocyte cholinesterase inhibition was observed at 15 days than at term. As was true in the chronic study, there was a poor dose response for both enzymes. Based on HED's preliminary evaluation of the 28-day dog study, these data, taken in conjunction with the chronic study, do not address the requirement for a 90-day dog study to satisfy HIARC's requirement.

2. 90-Day Inhalation Rat Toxicity Study: *EPA stated that it is requiring a new 90-day inhalation study in rats because the available 90-day study did not establish a NOEL.* *Cheminova believes that the submitted study did establish a NOEL for plasma, RBC, and brain cholinesterase inhibition. In the 90-day rat inhalation study, a clear NOAEL was established for plasma, RBC, and brain cholinesterase inhibition at 0.1 mg/L for males and females (see Table 5 below). The data show that cholinesterase inhibition in all three compartments at 0.1 mg/L is neither greater than 20% nor statistically significant.* *Cheminova believes that if new data are necessary, a tiered approach to the testing will be most appropriate.*	The selection of a LOAEL of 0.1 mg/L from the 90-day rat inhalation study was based not only on inhibition of plasma, RBC, and brain ChE activities but on treatment-related histopathological lesions seen in the respiratory epithelium of both sexes of rats at all concentrations tested. HED maintains that a new 90-day inhalation toxicity study in the rat is required to fully characterize the inhalation hazard of malathion.
V. SUPPORTED USE PATTERNS FOR MALATHION	
Cheminova's Comments	**HED's Response**
A. Government Programs*: Cheminova believes that separate risk assessments for the boll weevil eradication program, the MedFly eradication program, and the public health use for adult mosquito control should be conducted and presented separately from typical agricultural uses of malathion.*	In the revised Occupational and Residential Exposure Assessment for Malathion, separate risk assessments have been conducted for malathion use in the boll weevil eradication program and the public health use for adult mosquito control.
B. MALATHION REGISTRATIONS ***2. Registered End-Use Products*** *Cheminova is supporting only the following formulations of malathion: Emulsifiable Concentrates (EC); Ultra Low Volume (ULV); Dusts; Ready ToUse (RTU); and Wettable Powders (WP). No other formulation type should be included in the Agency's risk assessments.* *Regarding malathion dust formulations, Cheminova notes that it is supporting the use of this formulation only for certain agricultural uses (dates and stored grains). Cheminova is not supporting malathion dust formulations for non-agricultural and residential uses.*	No formulations other than those listed by Cheminova have been assessed. The dust formulation for homeowner use was addressed because this formulation may currently be found in the marketplace under another registrant's label.

C. Supported Food/Feed Uses and Use Patterns*: At this time, Cheminova is supporting the use patterns identified in Tables 6 through 10 for reregistration. These proposed use patterns are based on the residue data that have been submitted to the Agency. Cheminova will be discussing with grower groups the adequacy of these proposed use rates as well as how malathion is typically used in the field. We encourage the Agency to hold similar discussions. These discussions may identify changes to one or more parameters defining the use patterns for these crops (e.g., maximum single application rate, maximum number of applications per year, application interval, etc.).* *The tables in EPA's documents do not clearly present the use patterns that Cheminova intends to support for reregistration. Cheminova recommends that EPA include tables similar to the following tables in its documents.*	HED has conducted a cursory comparison of the proposed maximum single application rates, maximum, number of applications per year, and application intervals in Tables 6 through 10 and those provided to the Agency by Cheminova on December 22, 1997 (Pages 1-21 Malathion Field Practices/Test Rates) and finds considerable differences between the two documents. Until such time Cheminova provides the Agency with specific mitigation proposals, HED will continue to utilize Cheminova's Field Practices/Test Rates (December 22, 1997) in its dietary and/or occupational/non-occupational risk assessments. HED has conducted its risk assessments based on the supported uses and use patterns in accordance information from the December 10, 1997 "Smart Meeting" document, Cheminova's December 22, 1997 document (Pages 1-21 Malathion Field Practices/Test Rates) and Cheminova's March 10, 1998 letter. HED also believes it has presented this information clearly and refers Cheminova to Table A2 in the Residue Chemistry Chapter dated 14-April-1999.
D. Supported Non-food/feed Uses and Use Patterns *As stated in Cheminova's March 10, 1998, letter, the following non-agricultural uses will not be supported for reregistration: homeowner lawns; ornamental lawns and turf; and golf course turf. Cheminova will remove these unsupported uses from its label in response to a requirement in the final Reregistration Eligibility Decision (RED) document for malathion.*	HED acknowledges Cheminova's comment.
E. Malathion Labels: *As the primary registrant that has submitted the generic data to support malathion registrations, Cheminova agrees with HED's recommendation (page 3 of the April 14, 1999, draft Residue Chemistry Science Chapter) that following the issuance of the final RED, EPA must require all malathion registrants to amend their end-use product labels to make them consistent with the basic producer label. Cheminova is willing to assume a leadership role in working with EPA and the end-use registrants to make these revisions.*	HED acknowledges Cheminova's comment.
VIII. OCCUPATIONAL AND RESIDENTIAL EXPOSURE RISK ASSESSMENTS ***A. EPA INCLUDED TWO RISK ASSESSMENTS IN ITS PRELIMINARY DRAFT RED.***	

MALATHION: HED Phase 2 Comments on Cheminova A/S 30-day (error only) Response to the HED RED Preliminary Risk Assessment dated February 10, 2000.

Cheminova's Comment	**HED's Response**
In its draft RED, EPA included two versions of the occupational and residential risk assessment: "Malathion: Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document" dated 9/99 and "Malathion: Preliminary Risk Assessment for the Reregistration Eligibility Decision (RED) Document, Revised to Include Cancer Assessment Review Committee Conclusions." dated 2/2000. The existence of two risk assessments results in considerable confusion ....Cheminova requests that any revisions to the risk assessment be presented in just one document.	The Preliminary Risk Assessment 10-February-2000 is intended to provide, in a single document, summary information and data from a number of contributing disciplinary sections, such as the Occupational and Residential Exposure and Risk Assessment, which is included as an attachment. Both the Preliminary Risk Assessment and the supporting Occupational and Residential Exposure and Risk Assessment Chapter will be revised.
1. Differences Between the 9/99 and 2/00 Malathion Risk Assessments	
Cheminova's Comment	**HED's Response**
a. Helicopter Application Exposures: *Consistent with current HED policy, EPA did not include exposure estimates for aerial application by helicopter in the 2/00 risk assessment, whereas such estimates were included in the 9/99 risk assessment.*	The supporting Occupational and Residential Exposure and Risk Assessment Chapter will be revised to reflect current HED policy for aerial application by helicopter.
b. Exposure Estimates: *The estimated exposures, aggregate risk indices, and cancer risks for some scenarios are different in the 9/99 and 2/00 risk assessment documents. These differences include but are not limited to:* ** The exposures and the Aggregate Risk Indices (ARIs) associated with ULV spray applications for mosquito control in the two reports do not match. From Table 18 in the 2/00 risk assessment (which presents cancer risks), it appears that the mosquito control scenarios were calculated assuming an application rate of 0.23 lb a.i./acre, whereas an application rate of 0.50 lb a.i./acre was assumed in the 9/99 assessment. Cheminova requests that EPA use the application rate of 0.23 lb a.i./acre in the revised risk assessment.* ** For applying sprays with a groundboom sprayer, the cancer risk estimates for several crops do not match in the 9/99 and 2/00 risk assessments.*	Some existing registered products include mosquito ULV treatment at the 0.5 lb ai/acre rate, and therefore this rate was used to assess workers engaged in this application scenario. For post-application residential exposure, a refined use rate was desired. From interactions with mosquito control authorities in Florida and elsewhere, it was determined that the use rate of 0.23 lb ai/acre was appropriate. EPA will consider changing the rate used for workers after reviewing the possibility of the 0.5 lb ai/acre rate being inappropriate for any mosquito ULV application. ***Because a quantitative cancer risk assessment is not required, these sections have been dropped from the document.***

MALATHION: HED Phase 2 Comments on Cheminova A/S 30-day (error only) Response to the HED RED Preliminary Risk Assessment dated February 10, 2000.

B. OCCUPATIONAL APPLICATION EXPOSURE AND RISK ASSESSMENT	
Cheminova's Comment	**HED's Response**
1. Supported Crops and Uses: *EPA assessed occupational and residential exposures for application of malathion to lawns, including golf courses, sod farms, and ornamental lawns. However, as Cheminova pointed out in a March 10, 1998, letter to EPA, Cheminova is not supporting applications of malathion to residential lawns, ornamental lawns, or golf courses. Therefore, Cheminova requests that EPA remove these scenarios from its risk assessment.*	Because registrants, other than Cheminova, have turf use on their labels, EPA must currently include an assessment of the exposure and risks to these products. If turf use is ultimately agreed by all registrants of malathion to be removed from all registered product labels, then turf use will no longer be subject to assessment.
2. Agricultural Crop Groups and Assumed Application Rates: *Malathion is registered for use on a very large number of crops. Cheminova recognizes the necessity of creating groups of similar crops in order to simplify the occupational exposure assessment. However, the crop groups utilized by EPA in the draft occupational and residential risk assessment are difficult to understand and frequently incorrect.* *The maximum application rates assumed for each of these crop groups do not correspond to the maximum application rates that were tested in residue studies. Cheminova has identified the maximum tested application rate for each agricultural crop group and formulation. Cheminova requests that EPA perform its occupational exposure assessment using the crop groupings identified in 40 CFR, Part 180 and the maximum tested application rates identified in Table 11.*	EPA is reviewing its crop grouping categories and will clarify groupings by renaming as appropriate, and providing the identity of the crops belonging to each category. The groupings as they appear may require some adjustment regarding member crops, as well as, application rates. This is being reviewed by EPA, as well. However, the current approach to grouping and assignment of maximum use rates is believed to generally bracket the major use sites and maximum use rates for malathion agricultural application, and should serve that purpose until the Agency can conclude its review and make any necessary adjustments. Until such time Cheminova provides the Agency with specific mitigation proposals, HED will continue to utilize Cheminova's Field Practices/Test Rates (December 22, 1997) in the occupational exposure and risk assessment.
3. Application Rates on Ornamentals, Shade Trees and Pine Trees: *EPA assumed an application rate of 2.6 lb a.i./acre for ornamentals and pine trees. Cheminova is unsure how this application rate was derived and asks that EPA explain its derivation from the values required by the labels.*	It is possible the the application rate used was taken from another registrants's label, and that the label rate used is different from the one described by Cheminova. EPA will review the labels used, determine the appropriate application rate and revise, if appropriate. Also, EPA will determine if separate assessments for ornamentals and shade trees are appropriate.

4. Application Rate for Mosquito Control: *EPA assumed a maximum application rate of 0.5 lb a.i./acre for EC sprays for mosquito control. A review of labels suggests that this rate is applicable for thermal foggers. The maximum labeled application rate for EC sprays is 0.6 lb a.i./acre.* *In the 9/99 risk assessment, EPA states that the maximum application rate for ULV applications is 0.5 lb a.i./acre. Cheminova is unsure of the source of this application rate. As EPA has noted, the maximum application rate for ground foggers is 0.11 lb a.i./acre, and the rate for aerial ULV application is 0.23 lb a.i./acre. Since EPA based the postapplication assessment on these latter application rates, it is unclear why the mixer/loader/applicator assessment was based on an application rate of 0.5 lb a.i./acre. Cheminova notes that the 2/00 risk assessment utilized an application rate of 0.23 lb a.i./acre for ULV sprays for mosquito control. Cheminova suggests that EPA revise the exposure assessment to reflect the appropriate maximum application rate for ULV applications for mosquito control.*	Some existing registered products include mosquito ULV treatment at the 0.5 lb ai/acre rate, and therefore this rate was used to assess workers engaged in this application scenario. For post-application residential exposure, a refined use rate was desired. From interactions with mosquito control authorities in Florida and elsewhere, it was determined that the use rate of 0.23 lb ai/acre was appropriate. EPA will consider changing the rate used for workers after reviewing the possibility of the 0.5 lb ai/acre rate being inappropriate for any mosquito ULV application.
5. Application Rate for Berries: *EPA assumed a maximum application rate of 4 lb a.i./acre. However, as is shown in Table 11, the maximum tested application rate for berries is 2 lb a.i./acre for EC and WP formulations and 0.76 lb a.i./acre for ULV formulations. Cheminova recommends that EPA revise its risk assessment to reflect these application rates.*	EPA will review the rates used and compare to registered products as well as to the agreement regarding the use of maximum field test use rates.

6. Baseline Exposure Scenario: *In the occupational risk assessment, EPA has evaluated risks for three mitigation scenarios:* *(1) Baseline - representing exposure to an operator wearing long-sleeved shirt and long pants;* *(2) PPE-Mitigated - representing exposure to an operator wearing personal protective equipment (PPE); and* *(3) Engineering Controls - representing exposure to an operator associated with use of engineering controls (closed systems, enclosed cabs, water-soluble bags for wettable powder formulations, etc.).* *The baseline exposure scenario used by EPA violates the label PPE requirements and represents an illegal use of malathion. Cheminova urges EPA to remove baseline scenario exposure calculations from the risk assessments because their inclusion may mislead the public about the potential risks of using malathion.*	PPE required on many labels represent interim mitigation measures under the Worker Protection Standard (WPS), which were based on the results of acute toxicity of the end-use products. In the Reregistration Eligibility Decision (RED) process, toxicity endpoints for short-, intermediate-, and long-term exposures are assessed. It is necessary in assessing these new endpoints, to show the risks at baseline, as well as with PPE, or engineering controls, if the latter is necessary. If exposure scenarios do not trigger concern at the baseline clothing level, it is still necessary for the end-use product label to include any PPE required by the WPS based on acute effects.

7. Occupational Exposure Scenarios: *EPA included occupational exposure scenarios that should not be included in the risk assessment. Each of these scenarios is discussed individually below.*	
EPA inappropriately included a scenario - (7) applying sprays with a helicopter.	Helicopter application has been eliminated from the assessment. It is assumed that the assessment for fixed-wing aircraft will stand for helicopter use as well.
EPA included an exposure scenario - (11) applying with a handgun to turf - that does not represent an application method that is being supported for reregistration by Cheminova. Cheminova requests that EPA eliminate this exposure scenario from its risk assessment.	Turf uses currently may appear on labels from other registrants, and are therefore included in the risk assessment.
EPA has included an exposure scenario - (15) mixing/loading/applying with a paintbrush for mosquito control - that does not appear to be appropriate in the occupational risk assessment. Cheminova is unaware of any formulation labels that allow application by paintbrush to achieve mosquito control. Cheminova requests that EPA clarify what labels support this exposure scenario.	EPA will review labels to make sure that this is an application technique currently appearing. At this time, it is assumed to be included on a currently registered label.
The flagger scenario (16) is too broadly defined. Flaggers are assumed to be present for aerial applications on agricultural crops....and for mosquito control with both EC and ULV formulations. Given the very high treatment areas for mosquito control (1,500 acres for EC formulations and 7,500 acres for ULV formulations), use of human flaggers for mosquito control applications is not feasible. EPA should eliminate the evaluation of human flaggers for mosquito control.	Flagger scenarios are being reviewed for the appropriateness of assessing human flaggers for some large area aerial applications.

8. Assumptions for Daily Acres and Volumes Treated *a. Low-Pressure Handwand: EPA assumed that a low-pressure handwand would be used to treat 5 acres of ornamentals. In recent risk assessments for other pesticides (e.g., dimethoate), EPA assumed a volume-based application rate of 40 gallons per day. Unless there is a rationale for the different value assumed in the malathion risk assessment, Cheminova requests that EPA recalculate all low-pressure handwand scenarios assuming a use rate of 40 gallons per day.* *b. Backpack Sprayer: As above* *c. Handgun Sprayer: EPA has assumed a treatment rate of 5 acres per day when applying malathion to turf using a handgun sprayer. This scenario should be removed from the assessment because Cheminova is not supporting turf applications for reregistration.*	(a and b) EPA is reviewing this issue and will revise the assessment as appropriate. (c) Turf uses currently may appear on labels from other registrants, and are therefore included in the risk assessment.

9. PPE Assumptions: *Cheminova recognizes that the personal protective equipment (PPE) requirements on current malathion product labels are inconsistent. At present, most Cheminova labels require that handlers wear long-sleeved shirts, long pants, socks, shoes, and chemical- or water-resistant gloves. Additional requirements seen on some current labels include headgear for overhead exposures and protective eyewear. Cheminova will be holding discussions with stakeholders to determine a consistent set of PPE requirements for malathion products. In addition to the current minimum requirements, options being considered include coveralls and dust/mist filtering respirators. Cheminova will advise EPA of the outcome of these discussions at the nearest opportunity in the hope that EPA will incorporate the PPE requirements in the revised risk assessment.*	Unit exposure values from PHED or data from which protection factors can be applied are not available for certain of the PPE mentioned by Cheminova (i.e., headgear and protective eyewear). These PPE mitigation measures are not able to be quantitatively incorporated into the risk assessment. It is further noted that requirements for handlers to wear protective eyewear are based on the eye irritation potential of the end-use product. EPA does not believe it appropriate to establish a protection factor for protective eyewear in risk assessments limited to the active ingredient.
Cheminova notes that EPA applied PPE assumptions in an effort to generate acceptable exposures for the various scenarios. For example, gloves were assumed for some scenarios and respirators were included in others. EPA's resultant exposure assessment utilized a variety of assumptions regarding PPE. However, Cheminova requests that EPA include a single set of PPE requirements consistently throughout its risk assessment. There will be no need for EPA to estimate exposures based on incremental PPE requirements because the minimum set will have been determined by Cheminova.	Incremental assessment of additional PPE is in keeping with the WPS concern for not adding unnecessary clothing and equipment that may add heat stress and physical burden to workers. In some cases the PPE necessary to mitigate risks that are based upon short-, intermediate- or long-term toxicity endpoints used in the RED process are the same as those that are required under the WPS requirements for acute toxicity from the end-use product.

MALATHION: HED Phase 2 Comments on Cheminova A/S 30-day (error only) Response to the HED RED Preliminary Risk Assessment dated February 10, 2000.

10. Unit Exposure Calculations:	
Cheminova's Comment	**HED's Response**
a. Enclosed Cab Airblast Application*: For enclosed cab scenarios, EPA assumed that applicators would not wear PPE, which is consistent with the Worker Protection Standard (WPS). However, there are no data in PHED to estimate enclosed cab, "no gloves" hand exposure for airblast application. Therefore, EPA estimated the enclosed cab, "no gloves" hand exposures by back-calculating from the enclosed cab, "gloves" hand exposure assuming a 90% reduction factor for wearing gloves. Thus, EPA estimated a total dermal unit exposure of 0.14 mg/lb a.i. for enclosed cab airblast application.* *However, on page 10 of the PHED Surrogate Exposure Guide, a protection factor of 98% is recommended to estimate exposure reduction associated with enclosed cabs. Therefore, Cheminova proposes estimating the enclosed cab, "no gloves" hand exposure for airblast sprayer application by applying a 98% reduction factor to the open cab, "no gloves" hand exposure. If this approach is taken, the estimated total dermal unit exposure is 0.0085 mg/lb a.i. Cheminova recommends that EPA use this value to estimate dermal exposures associated with enclosed cab airblast application.*	Application of PPE or engineering control protection factors to PHED scenarios that do not have empirical data for the desired level of mitigation has been a routine procedure in assessing worker exposure potential. Application of such protection factors is made with the caveat that a level of uncertainty is introduced by so doing. In the cited example, it was believed that creating a "no-gloves", enclosed cab airblast application scenario by back-calculating (i.e., removing) the assumed protection factor that is reflected in the empirical data for a gloved applicator in an enclosed cab, would result in less uncertainty than adding a protection factor for enclosed cabs to the PHED unit exposure for the "open-cab" airblast applicator that is not wearing gloves. This is because the protection factor for "enclosed" cabs was based originally on a flagger scenario, where exposure potential is lower than for applicators in general. Therefore, the approach taken will not be changed.
b. Fogger Application: *Because PHED contains no data appropriate for estimating exposures associated with application by foggers, EPA used the unit exposure estimates for airblast application as a surrogate. Cheminova believes this is a reasonable assumption given the lack of data. However, Cheminova suggests that, for enclosed cab application, EPA use the dermal unit exposure estimate of 0.0085 mg/lb a.i. as calculated above rather than EPA's estimate of 0.14 mg/lb a.i.*	See response above.
c. Paintbrush Application*: As previously discussed above, Cheminova is unaware of any formulation labels that allow paintbrush application for mosquito control. Consequently, Cheminova requests that this scenario be removed from the risk assessment.*	EPA will review labels to verify the listing of this use.

C. OCCUPATIONAL POSTAPPLICATION EXPOSURE AND RISK ASSESSMENT	
Cheminova's Comment	**HED's Response**
1. Postapplication Exposure Scenarios: *Cheminova is not supporting applications of malathion to turf.*	Because registrants, other than Cheminova, have turf use on their labels, EPA must currently include an assessment of the exposure and risks to these products. If turf use is ultimately agreed by all registrants of malathion to be removed from all registered product labels, then turf use will no longer be subject to assessment.
2. Crop Groups and Application Rates: *EPA applied the default transfer coefficients to crop groups in the occupational postapplication risk assessment. Cheminova suggests that the reentry risk assessment be revised to reflect the maximum application rates and crop groups recommended for the occupational risk assessment.* *A further refinement of the postapplication assessment would allow for the most complete understanding of potential postapplication risks on a crop-by-crop basis. To accomplish this, Cheminova requests that EPA assess postapplication exposures for the application of each formulation onto each crop at the crop-specific application rate and using the most relevant transfer coefficients. Cheminova believes that the crop group approach employed by EPA does not provide sufficient detail to completely understand postapplication risks and the appropriate reentry intervals.* *EPA assumed an application rate of 2.0 lb a.i./acre on mushrooms in the postapplication assessment; however, the application rate for mushrooms, 0.039 lb a.i./1,000 ft2, is equivalent to 1.7 lb a.i./acre. Cheminova requests that EPA recalculate postapplication exposures for mushrooms using the correct application rate.*	EPA is reviewing its crop grouping categories and will clarify groupings by renaming as appropriate, and providing the identify of the crops belonging to each category. The groupings as they appear may require some adjustment regarding member crops, as well as, application rates. This is being reviewed by EPA, as well. However, the current approach to grouping and assignment of maximum use rates is believed to generally bracket the major use sites and maximum use rates for malathion agricultural application, and should serve that purpose until the Agency can conclude its review and make any necessary adjustments. Crop groupings for the purpose of assessing applicator exposure are not necessarily appropriate for assessing postapplication exposure. The former crop grouping must take into account appropriate application techniques (i.e., equipment types), whereas, the latter must be grouped according to major factors that affect postapplication exposure (e.g., foliage canopy, cultural practices, etc.). EPA will verify label application rates and make revisions as appropriate.

3. Transfer Coefficients: *EPA applied the default transfer coefficients to crop groups in the occupational postapplication risk assessment. Where available, EPA should use the transfer coefficients measured in a number of studies conducted by the Agriculture Reentry Task Force (ARTF), of which Cheminova is a member. Cheminova believes that the ARTF transfer coefficients demonstrate that the EPA defaults considerably overstate the true values.*	EPA acknowledges that empirically-supported transfer coefficients are, or have been developed by the ARTF. Some of these studies are being reviewed in EPA currently, but all are considered draft at this point in time. Default TCs currently used in the assessment have been developed as described by the registrant, and serve as the best available standard values for use in the malathion assessment at this time.
4. Postapplication Occupational Cancer Risks: *LADDs were estimated assuming that exposures would occur 40 days per year. Cheminova is unsure how EPA derived the value of 40 days to describe postapplication exposure frequency.*	The current cancer classification does not require quantification of postapplication occupational cancer risk; this section has been removed from the revised risk assessment.
5. Presentation of Postapplication Results: *In the 9/99 risk assessment, exposures and MOEs are explicitly calculated for each day following application. In the 2/00 risk assessment, however, this detail is lost, and the only information presented consists of a summary of estimated reentry intervals. Cheminova finds the approach in the 2/00 assessment to be lacking in detail, and it obscures the calculations made for the postapplication assessment. Therefore, Cheminova requests that EPA include occupational postapplication calculations in the revised risk assessment.*	The Preliminary Risk Assessment 10-February-2000 is intended to provide, in a single document, summary information and data from a number of contributing disciplinary sections, such as the Occupational and Residential Exposure and Risk Assessment, which is included as an attachment. Both the Preliminary Risk Assessment and the supporting Occupational and Residential Exposure and Risk Assessment Chapter will be revised.
D. RESIDENTIAL APPLICATION EXPOSURE AND RISK ASSESSMENT, 1. Exposure Assumptions	
Cheminova's Comments	**HED's Response**
a. Lawn Application: *Cheminova is not supporting application of malathion products to turf, either by homeowners or commercial applicators.*	Because registrants, other than Cheminova, have turf use on their labels, EPA must currently include an assessment of the exposure and risks to these products. If turf use is ultimately agreed by all registrants of malathion to be removed from all registered product labels, then turf use will no longer be subject to assessment.
b. Hose-End Sprayer Application: *EPA assumed that homeowners would apply 50 gallons of spray with a hose-end sprayer for use on fruit trees, ornamentals, vegetables/small fruit gardens, and mosquito control.*	The standard assumption of 5 gallons of spray per day from EPA's 1997 Standard Operating Procedures (SOPs) for Residential Risk Assessments will be used for these uses in the revised assessment.

c. Body Weight: *In the residential exposure assessment, EPA assumed an average body weight of 70 kg. However, the SOPs recommend an average body weight of 71.8 kg. Cheminova requests that EPA incorporate the appropriate default value for body weight into the residential exposure assessment.*	After the Draft SOPs were developed, discussions among participating representatives for NAFTA agreed that the 70 kg body weight was more appropriate. The 71.8 kg value was thought to imply a precision that was not appropriate.
d. Application Rates for Homeowner Uses: *EPA has assumed incorrect application rates for homeowner uses of EC formulations on fruit trees, ornamentals, and vegetables.*	Registered products, other than Cheminova's may have higher use rates. EPA will verify labeled use rates and make any revisions as needed.
E. RESIDENTIAL POSTAPPLICATION EXPOSURE AND RISK ASSESSMENT	
Cheminova's Comment	**HED's Response**
1. Turf-Related Exposure Scenarios: *EPA calculated postapplication exposures to residents contacting treated turf. However, because Cheminova is not supporting reregistration of malathion for treatments to turf, these postapplication exposures should be removed from the exposure assessment.* *Cheminova recognizes that spraying malathion to achieve mosquito control may result in residues being present on turf. Consequently, Cheminova believes that postapplication exposure scenarios involving turf should be limited to those involving residues resulting from mosquito control spraying.*	Because registrants, other than Cheminova, have turf use on their labels, EPA must currently include an assessment of the exposure and risks to these products. If turf use is ultimately agreed by all registrants of malathion to be removed from all registered product labels, then turf use will no longer be subject to assessment.
2. Deposition Following Mosquito Control Uses: *EPA used AgDRIFT to estimate the deposition of malathion following aerial spraying. Unfortunately, EPA did not provide any information in the residential postapplication exposure assessment about the inputs that were used in the AgDRIFT model.*	Important input parameters used in the model have been included in the revised document.

3. Body Weight Assumption: *In the residential postapplication exposure assessment, EPA assumed an average body weight of 70 kg. However, the SOPs recommend an average body weight of 71.8 kg. Cheminova requests that EPA incorporate the correct default value for body weight into the residential postapplication exposure assessment.*	After the Draft SOPs were developed, discussions among anticipating representatives for NAFTA agreed that the 70 kg body weight was more appropriate. The 71.8 kg value was thought to imply a precision that was not appropriate.
4. Application Rate Assumptions: *In estimating the dislodgeable foliar residues (DFRs) for malathion on garden plants and pick-your-own strawberries, EPA assumed that 5 gallons of spray (0.023 lb ai/gal) would be applied to an area of 1,000 ft2. EPA also assumed that 5 gallons of spray (0.034 lb ai/gal) would be applied to ornamentals in an area of 2,000 ft2. Cheminova believes that the application rates used by EPA are incorrect.*	EPA will verify application rates used in its assessment and make any needed revisions as appropriate.
5. Cancer Risk Assessment Exposure Assumptions: *EPA has assumed that all "residential" use of malathion would be associated with 5 postapplication exposure days per year. Cheminova is unsure of the foundation for this assumption. The assumption of 5 days per year at commercial "pick your own" strawberry farms appears to be too high.*	The current cancer classification does not require quantification of residential postapplication cancer risk; this section has been removed from the revised risk assessment.